

Investor Update

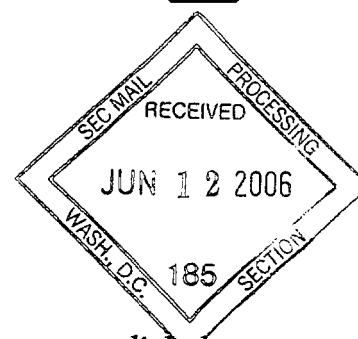
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More breast cancer patients to be saved as Herceptin is given green light by the National Institute for Health and Clinical Excellence (NICE)

One of the fastest ever appraisals by NICE confirms cost effectiveness of Herceptin

NICE has confirmed the cost effectiveness of Herceptin in early stage HER2 positive breast cancer and recommended its use across England and Wales. This approval has been granted in a little over two weeks since the European Commission approved the use of Herceptin in this particularly aggressive form of the disease. In a similar move, the Scottish Medicines Commission (SMC) has issued simultaneous guidance in Scotland recommending its use across Scottish Health Boards.

NICE has concluded that Herceptin is cost-effective. This was based on an analysis, which included a submission from Roche suggesting that the standard unit of measurement to estimate the cost-effectiveness of a treatment, known as a cost per QALY (Quality Adjusted Life Year) is £2387. This is well below commonly accepted thresholds for other commonly prescribed treatments, such as statins.

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HER2-positive breast cancer, which affects approximately 20-25%¹ of women with breast cancer, demands special and immediate attention because the tumours are fast-growing and there is a high likelihood of relapse. The Department of Health has previously estimated that the widespread use of Herceptin in early stage HER2 positive breast cancer would save at least 1000 lives a year. The actual number of lives saved may ultimately be higher as experts are now suggesting that, without Herceptin, up to two thirds of patients with HER2 positive breast cancer may go on to develop late stage and terminal disease. Each year nearly 9,000¹ UK women will be diagnosed with early-stage HER2-positive breast cancer, at a point where the cancer is still curable.

"Herceptin is the most important treatment advance ever for women with early stage HER2 positive breast cancer and therefore today's announcement is excellent news for all these women throughout the UK," said Professor Ian Smith, Head of the Breast Unit at the Royal Marsden

Hospital, London and the lead UK investigator for HERA. "Testing for HER2 status on diagnosis and access to Herceptin treatment should now be made available as soon as possible to all patients likely to benefit."

John Melville, General Manager of Roche Products Ltd, added, "We are absolutely delighted that both NICE and the SMC have shown such a commitment to improving the prognosis of women with breast cancer and worked so hard to prioritise the review of Herceptin by issuing draft guidance roughly two weeks after we gained a licence for its use in early stage HER2 positive breast cancer. This is great news for women with this aggressive form of such a devastating disease".

This recommendation from NICE will be published as final guidance in July unless there are appeals lodged from stakeholders such as Roche and patient groups. Following publication of final guidance Primary Care Trusts (PCTs) and NHS Trusts, which manage the implementation of NICE approved therapies, will have a maximum of three months in which to fully implement use of the treatment, which has been shown to reduce the risk of cancer recurrence by roughly half and significantly improve survival in patients with an otherwise poor prognosis

New data Herceptin presented, last week, at this year's influential American Society of Clinical Oncology (ASCO) meeting demonstrates that within just two years Herceptin already reduces the risk of death by 34%ⁱⁱ for breast cancer patients with early-stage HER2-positive breast cancer. A survival benefit of this magnitude is rarely seen within five years in cancer therapy. These data add to the earlier impressive HERA (HERceptin Adjuvant) resultsⁱⁱⁱ that showed Herceptin following standard chemotherapy reduces the risk of relapse by 46% compared to chemotherapy alone.

It was on the basis of these results that on 23 May 2006, a licence was granted by the European Commission for the use of Herceptin following surgery and standard chemotherapy for early stage HER2 positive breast cancer. Five studies involving over 13,000 women worldwide with early stage HER2 positive breast cancer have all consistently shown that Herceptin reduces the risk of cancer recurrence by roughly half.^{iv}

As with most treatments there are side-effects associated with Herceptin. Herceptin alone is not known to cause cardiotoxicity. However, routine treatments for breast cancer such as radiotherapy and anthracyclines (chemotherapy) are associated with damage to the heart. Herceptin seems to delay this damage being repaired and may lead to a risk of cardiotoxicity ranging from 0.54% to 4%, depending upon the accompanying chemotherapy^{iii,iv}. In the majority of patients these effects are of short duration and reversible. As with any treatment for cancer a

breast cancer patient should make a decision jointly with his or her doctor to see what the most beneficial course of action would be and whether the benefit of treatment would outweigh the small risk of an adverse reaction.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative products and services for the early detection, prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. In 2005 sales by the Pharmaceuticals Division totalled 27.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.2 billion Swiss francs. Roche employs roughly 70,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet (www.roche.com).

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ⁱ Johnston SRD et al. SABCC 2003 abs 512.

ⁱⁱ Smith I. Abstract presented at the American Society for Clinical Oncology congress, June 2006.

ⁱⁱⁱ Piccart-Gebhart M, Procter M, Leyland-Jones B, et al. A Randomized Trial of Trastuzumab Following Adjuvant Chemotherapy in Women with HER2 Positive Breast Cancer. *New England Journal of Medicine* 353:16 2005.

^{iv} Romond EH, Perez EA, Bryant J, Suman VJ, Geyer CE Jr, Davidson NE, et al. Trastuzumab plus adjuvant chemotherapy for operable HER2-positive breast cancer. *New England Journal of Medicine* 2005;353:1673-84.